

REMARKS

Upon entry of this amendment, claims 38, 39, 40, 44, 45, 46, 48, 49, 50, 54, 57, 58, 62, 64, 65, 70, 71, and 72 will be pending in the application. Claim 38 is amended to incorporate the limitation of claim 59 and to remove the phrase “one or two amino acid sequences.” Claim 44 is similarly amended. Claims 49, 50, 54, 57, 64, 65, 70, and 71 are amended to provide antecedent basis in view of the amendments to claims 38 and 44. Claims 71 and 72 are withdrawn. Claims 1-37, 41-43, 47, 51-53, 55, 56, 59-61, 63, and 66-69 are canceled. No new matter is introduced.

Claims 71 and 72 should be rejoined.

As an initial matter, Applicants traverse the withdrawal of claims 71 and 72 for allegedly being directed to nonelected species. Claim 71 as amended herein recites “[t]he polynucleotide of claim 38, said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprising the amino acid sequence of SEQ ID NO: 27.” Claim 72 recites “[a]n isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 27.” The polynucleotides set forth in claims 71 and 72 would have been encompassed within the search of the elected species of a polynucleotide comprising a nucleotide sequence encoding SEQ ID NO:10 and thus do not impose an additional search burden upon the Examiner. Rejoinder of claims 71 and 72 is thus respectfully requested.

The objection to the specification should be withdrawn.

An objection to the specification is raised for alleged lack of support of claim 68. Applicants disagree with the objection. Nonetheless, in an effort to advance prosecution of the application and without conceding the propriety of the objection, claim 68 is canceled. The objection should thus be withdrawn.

Obviousness-type double patenting rejections

Claims 38-40, 44, 49, 50, 54, 59, 62, 64, 65, and 68 are provisionally rejected for alleged obviousness-type double patenting over claims 39 and 40 of copending U.S. Appl. No. 11/580,632. Applicants request that the rejection be held in abeyance pending an

indication of allowable subject matter in the present application or in U.S. Appl. No. 11/580,632.

Claims 38-40, 44, 49, 50, 59, 62, 65, 68, and 70 are rejected for alleged obviousness-type double patenting over claims 1, 3, 4, 6, and 7 of U.S. Patent No. 6,090,611. Applicants submit herewith a terminal disclaimer over U.S. Patent No. 6,090,611. The rejection should thus be withdrawn.

The new matter rejection should be withdrawn.

Claims 44, 45, 46, 49, 50, 54, 56, 57, and 68 are rejected under 35 U.S.C. § 112, first paragraph for allegedly containing new matter. Applicants disagree with the rejection. Nonetheless, without conceding the propriety of the rejection and in an effort to advance prosecution of the application, Applicants have canceled claim 68. Applicants also have amended claim 44 to recite “[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO:10.” Exemplary support for the claim is located in Figure 4 of the specification. Withdrawal of the rejection is respectfully requested.

The rejection of claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68, and 70 for alleged indefiniteness should be withdrawn.

Claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68, and 70 are rejected under the second paragraph of section 112 for alleged indefiniteness.

The Examiner asserts that claim 38 is indefinite and confusing in recitation of ““at least 15 contiguous nucleotides from ... SEQ ID NO: 4, wherein said polynucleotide encodes a polypeptide comprising one or two ... SEQ ID NO: 10.”” Office Action, page 6. Claim 48 is similarly rejected for reciting “at least 15 contiguous nucleotides from nucleotide position 2776 to nucleotide position 3466 of the nucleotide sequence of SEQ ID NO: 4.” *Id.* The Examiner states that it is unclear how a ten contiguous amino acid-long polypeptide can be encoded by 15 contiguous nucleotides from SEQ ID NO:4. *Id.* Applicants disagree with the rejection. Nonetheless, without conceding the propriety of the rejection and in an effort to

advance prosecution of the application, claim 38 has been amended to recite “[a]n isolated polynucleotide comprising at least 15 contiguous nucleotides from the nucleotide sequence of SEQ ID NO: 4, said polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprising the amino acid sequence of SEQ ID NO: 10.” The amendment to the claim clarifies that the *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO:10 and the polynucleotide comprises at least 15 contiguous nucleotides from the nucleotide sequence of SEQ ID NO:4. The claim allows but does not require that the recited “at least 15 contiguous nucleotides” encode the amino acid sequence of SEQ ID NO:10. Because one skilled in the art would understand the metes and bounds of the claimed subject matter, the rejection should be withdrawn.

Claim 44 also is rejected for alleged indefiniteness in recitation of the phrase “at least five contiguous amino acids from ... SEQ ID NO:5, wherein said polypeptide comprises ... two amino acid sequences of SEQ ID NO:10.” *Id.* Without conceding the propriety of the rejection and in an effort to advance prosecution of the application, claim 44 is amended to recite “[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO:10.” Because one skilled in the art would understand the metes and bounds of the claimed subject matter, the rejection should be withdrawn.

The rejection of claims 38-40, 44-46, 48-50, 54, 56-59, and 62-66 over the Covacci reference should be withdrawn.

Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66, and 68 are rejected under section 102(b) for alleged anticipation by Covacci *et al.*, *PNAS*, 1993, 90:5791-5795 (“the Covacci reference”). Applicants disagree with the rejection. Without conceding the propriety of the

rejection, claim 68 is canceled and claim 38 is amended herein to recite “[a]n isolated polynucleotide comprising at least 15 contiguous nucleotides from the nucleotide sequence of SEQ ID NO: 4, said polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprising the amino acid sequence of SEQ ID NO: 10.” Claim 44 is amended herein to recite “[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO:10.” The claims are fully supported by Figure 4 of International Appl. No. PCT/EP93/00472, filed March 2, 1993. Because the Covacci reference is not prior art to the present claims, the rejection should be withdrawn.

The rejection of claims 44-46 and 56 over the Peterson reference should be withdrawn.

Claims 44-46, 56, and 68 are rejected under section 102(b) for alleged anticipation by Peterson et al., Nature, 1991, 354:369-373 (“the Peterson reference”). Without conceding the propriety of the rejection, claim 68 is canceled and claim 44 is amended herein to recite “[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO:10.” It has not been established on the present record that the Peterson reference teaches an isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5 as presently claimed. The rejection should thus be withdrawn.

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PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested. Should any issues remain unresolved by the present remarks, the Examiner is invited to contact the undersigned at 215.568.3100.

Respectfully submitted,

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Terminal Disclaimer over U.S. Patent No. 6,090,611

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